

### **REMARKS**

This paper is filed in response to the Final Office action mailed on June 23, 2006. In the Office action, claims 1-21 stand rejected; in response claims 1-21 have been cancelled and claims 22-41 have been added. Please amend the above-identified U S patent application prior to examination on the merits.

Claims 1-9, 11-13, and 17-19 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Japanese Patent No. 02-182259 ("Yasushi"). In response, applicant has cancelled claims 1-21 and submitted a new set of claims 22-41 for examination. Moreover, applicant believes that the new set of claims includes one or more element that is not disclosed by Yasushi, thereby obviates the aforementioned rejection, as discussed more specifically in the paragraphs hereinafter.

New independent claim 22, as well as claims 23-33 dependent directly or indirectly thereon, specifies a biocompatible, hemostatic, cross-linked gelatin composition including a preformed, cross-linked gelatin sponge and a wetting agent, wherein the wetting agent is coated on the surface of the gelatin sponge and lowers the surface tension of an aqueous solution thereby facilitate the spreading and penetration of the solution into the gelatin sponge.

Similarly, independent claim 34, as well as claims 35-38 dependent directly or indirectly thereon, specifies a method for decreasing the hydration time of a cross-linked gelatin composition including a preformed, cross-linked gelatin sponge and a wetting agent, wherein the wetting agent is coated on the surface of the gelatin sponge and lowers the surface tension of an aqueous solution thereby facilitate the spreading and penetration of the solution into the gelatin sponge. As a result, the wetting agent coated on the surface of the gelatin sponge allows a uniform and expeditious wetting of the gelatin sponge in the presence of an aqueous solution.

In addition, independent claim 39, as well as claims 40 and 41 dependent thereon, specifies a kit of parts for preparing a biocompatible, hemostatic, cross-linked gelatin composition, wherein the kit includes a syringe and a non-hydrated pledget, said pledget consisting of a wetting agent coated on a preformed, cross-linked gelatin sponge, which

wetting agent lowers the surface tension of an aqueous solution thereby facilitate the spreading and penetration of the aqueous solution into the gelatin sponge.

Yasushi does not disclose, suggest or claim a cross-linked gelatin composition including a wetting agent coated on the surface of a preformed, cross-linked gelatin sponge to permit uniform and expeditious wetting of the gelatin in the presence of an aqueous solution, as recited by the new set of claims.

In fact, Yasushi discloses a hemostatic sticking plaster. As noted in the last paragraph of page 4 of Yasushi, the plaster is formed by: (1) adding a surfactant to an aqueous solution of gelatin; (2) stirring the solution to form a foam and freeze-drying the foam to obtain an sponge; and (3) soaking the sponge in an organic solvent solution containing a cross-linking agent in order to cross-link the gelatin or the like.

The surfactant disclosed in Yasushi is added to an aqueous solution of gelatin prior to the foaming of the gelatin solution to form the gelatin sponge. As a result, the surfactant in Yasushi is impregnated in the gelatin sponge, instead of coated on the surface of same, as disclosed and claimed in the current application. Moreover, Yasushi discloses the use of the surfactant to cause foaming of the gelatin solution, instead of lowering the surface tension of an aqueous solution that is to be absorbed by the gelatin sponge.

Although Yasushi disclosed the soaking of the gelatin sponge in an organic solution of a cross-linking agent, the cross-linking agent is not a surfactant, much less a wetting agent.

Yasushi further discloses providing a water-absorbing polymer layer around the gelatin sponge to absorb blood when the bleeding exceeds the blood-arrest capacity of the gelatin sponge. As a result, the polymer layer is structurally and functionally detached from the gelatin sponge, and therefore irrelevant of the subject matter of the current invention.

In summary, Yasushi fails to disclose a cross-linked gelatin sponge that is coated with a wetting agent, much less a gelatin sponge coated with a wetting agent to lower the surface tension of an aqueous solution to be absorbed therein. Yasushi does not disclose each of the elements recited by the new set of claims, it follows that the claims are not anticipated thereby. In addition, Yasushi fails to disclose or suggest that it would be desirable or even possible to coat a wetting agent on the surface of a cross-linked gelatin sponge, and hence a *prima facie* case of obviousness has not been established. See *In re Sernaker*, 217 U.S.P.Q. 1 (Fed. Cir. 1983) and *Ex parte Clapp*, 227 U S P.Q. 972, 973 (Bd. Pat. App. 1985).

Turning to the rejections based upon the obviousness. Claims 14-16, 20, and 21 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over Yasushi in view of U.S. Patent No. 6,063,061 ("Wallace")<sup>1</sup>. In response, applicant has cancelled claims 1-21 and submitted a new set of claims 22-41 for examination on merit. Moreover, applicant believes with the new set of claims, the current application should not be rendered obvious over Yasushi in view of Wallace.

Independent claim 39, as well as claims 40 and 41 dependent thereon, recites a kit of parts including, among other things, a pledget consisting of a wetting agent coated on the surface of a cross-linked gelatin sponge, similar to independent claims 22 and 34 discussed supra. Neither Yasushi nor Wallace disclose or suggest this element.

The deficiencies of Yasushi are addressed above. Wallace is cited for allegedly disclosing an active agent, an amount of wetting agent in a gel after evaporation of a solvent, sterilizing and packaging the gel composition, and a kit. Wallace in no way teaches or suggests a wetting agent coated on the surface of a cross-linked gelatin sponge, and therefore no combination of Wallace and Yasushi teaches or suggests all of the elements of claim 16. Consequently, the new set of claims should not be rendered obvious over Yasushi in view of Wallace.

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<sup>1</sup> The Office action incorrectly refers to U.S. Patent No. 6,603,061 in this rejection. Applicants assume that the Examiner intended to refer to U.S. Patent No. 6,063,061.

Appl. Ser. No. 10/068,812  
Amdt. dated Sep. 19, 2006  
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An early action indicating the allowability of this application is respectfully requested. If a telephone call would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney. The undersigned verifies that he is authorized to act on behalf of the assignee of the present application.

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Respectfully submitted,

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